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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,562	01/22/2002	Ramaswamy Chandrashekhar	HW-8-2	9225

7590 02/27/2003

Heska Corporation  
1613 Prospect Parkway  
Fort Collins, CO 80525

EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
1645	7

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/054,562	CHANDRASHEKAR ET AL.
	Examiner	Art Unit
	Padmavathi v Baskar	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 21-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 21-36 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____

#### DETAILED ACTION

I. Applicant's amendment filed on 1/22/02 is acknowledged. Claims 1-20 have been canceled. Claims 21-36 have been added. Claims 21-36 are pending.

#### RESTRICTION

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 21-24, 27-31 drawn to Dirofilaria immitis protein and a composition classified in class 424 subclass 191.1 Further restriction to one SEQ.ID.NO required (see paragraph # 3).
- II. Claim 25 drawn to an isolated antibody classified class 530, subclass 387.1. Further restriction to one SEQ.ID.NO required (see paragraph # 3).
- III. Claim 26 drawn to a method for identifying a compound capable of inhibiting filariid cuticlin activity classified in class 435, subclass 5. Further restriction to one SEQ.ID.NO required (see paragraph # 3).
- IV. Claims 32- 36, drawn to a method to inhibit molting of filariid larvae in an animal classified in class 424, subclass 184.1. Further restriction to one SEQ.ID.NO required (see paragraph # 3).

#### DISTINCT INVENTIONS

3. For each group of inventions I-IV above, restriction to one of the following SEQ.ID.NO is also required under 35 USC 121. Therefore, election is required of one of inventions I - IV and one of SEQ ID NO: SEQ.ID.NO 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions; represent structurally different polypeptides as represented by SEQ ID NO: 4 and 9 and the

polynucleotides encoding them as represented by SEQ ID NO: 1, 2, 3, 5, 6, 7, 8, and 10. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects. Thus, each sequence is unique and patentably distinct since each sequence has a different structure with specific amino acid or nucleic acid and is identified by a specific SEQ.ID.NO. Therefore, restriction is deemed proper because these products appear to constitute patentably distinct inventions.

4. Inventions I and II are patentably distinct products, which are different structurally, functionally, and biochemically. Invention I is drawn to a polypeptide which comprises amino acids and is distinct from antibody in invention II because antibody has a different structure, inherent avidity, affinity and specificity that a simple protein is not capable of expressing.

Inventions III and IV are Patentably distinct methods. Invention IV is drawn to an *invivo* method to inhibit molting filariid larvae which requires animals and protein whereas Invention III is drawn to an *invitro* method to identify compounds that inhibit filariid cuticulin activity which does not require animals. Thus these two methods are different to each other utilizing different steps, reagents and result in different outcome.

5. Inventions I and III/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group I can be used in the production of raising antibodies or as a detection reagent for in vitro assays for the detection of antibodies.

6. Because these inventions are distinct for the reason given above, have acquired a separate status in the art as shown by their different classification, and while searches may overlap they are not coextensive, restriction for examination purposes as indicated is proper.

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7. Should applicant traverse on the ground that these inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing these inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 A.M. to 4:00 P.M. EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.  
2/24/03

*LYNETTE R. F. SMITH*  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600